

CLAIMS

- Sub A1*
1. 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, hydrochloride dihydrate characterised in that it:
- 5 (i) provides an infrared spectrum containing peaks at 3392, 2739, 1751, 1325 and 713 cm⁻¹; and/or
- (ii) provides an X-ray powder diffraction (XRPD) pattern containing peaks at 9.1, 12.0, 15.7, 16.3 and 19.8 °2θ.
- 10 2. A hydrate according to claim 1 which provides an infra red spectrum substantially in accordance with Figure I.
- 15 3. A hydrate according to claim 1 or claim 2, which provides an X-ray powder diffraction (XRPD) pattern substantially in accordance with Figure II
4. A hydrate according to any one of claims 1 to 3, in isolated form.
5. A hydrate according to any one of claims 1 to 4, in pure form.
- 20 6. A hydrate according to any one of claims 1 to 5, in crystalline form.
7. A process for preparing a hydrate according to claim 1, characterised in that 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione (Compound I) is treated with a suitable source of hydrochloride counter-ion and an appropriate amount of water for formation of the Hydrochloride Hydrate; and thereafter the required compound is recovered.
- 25 8. A pharmaceutical composition comprising an effective, non-toxic amount of a hydrate according to claim 1 and a pharmaceutically acceptable carrier therefor.
- 30 9. A hydrate according to claim 1, for use as an active therapeutic substance.
10. A hydrate according to claim 1, for use in the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof.
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11. The use of hydrate for the manufacture of a medicament for the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof.

5 12. A method for the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof, in a human or non-human mammal which comprises administering an effective, non-toxic, amount of hydrate to a human or non-human mammal in need thereof.

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